

Australia
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I am confident the implementation of these provisions will provide a sound basis on which to develop further cooperative arrangements between us on orphan drug products and to work toward a reciprocal arrangement in the future.

I look forward to your official confirmation these arrangements can be agreed.

Yours sincerely

Terry Slater
National Manager
Therapeutic Goods Administration
12 August 1997

[FR Doc. 97-29906 Filed 11-12-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97F-0450]

Nalco Chemical Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Nalco Chemical Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of an emulsifier blend containing sorbitan monostearate, polyoxyethylene (20) sorbitan monostearate, and polyoxyethylene (20) sorbitan monolaurate as an anti-corrosive agent in boilers where steam may contact food.

DATES: Written comments on the petitioner's environmental assessment by December 15, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Martha D. Peiperl, Center for Food

Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3077.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 7A4540) has been filed by Nalco Chemical Co., One Nalco Center, Naperville, IL 60568-1198. The petition proposes to amend the food additive regulations in § 173.310 *Boiler water additives* (21 CFR 173.310) to provide for the safe use of an emulsifier blend containing sorbitan monostearate, polyoxyethylene (20) sorbitan monostearate, and polyoxyethylene (20) sorbitan monolaurate as an anti-corrosive agent in boilers where steam may contact food.

The potential environmental impact of this action is being reviewed. To encourage public participation consistent with regulations promulgated under the National Environmental Policy Act (40 CFR 1501.4(b)), the agency is placing the environmental assessment submitted with the petition that is the subject of this notice on public display at the Dockets Management Branch (address above) for public review and comment. Interested persons may, on or before December 15, 1997, submit to the Dockets Management Branch (address above) written comments. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA will also place on public display any amendments to, or comments on, the petitioner's environmental assessment without further announcement in the **Federal Register**. If, based on its review, the agency finds that an environmental impact statement is not required and this petition results in a regulation, the

notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: October 28, 1997.

Alan M. Rulis,

*Director, Office of Premarket Approval,
Center for Food Safety and Applied Nutrition.*
[FR Doc. 97-29771 Filed 11-12-97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: October 1997

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of October 1997, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject City, State	Effective date
Program-Related Convictions	
ADEFIHAN, TITILAYO O, MILWAUKEE, WI	11/20/97
ALEXANDER, EDNA DENISE, DEVINE, TX	11/20/97
ALLEN, ANDREW JACKSON, WINSLOW, AZ	11/20/97
AMICUCCI, DIANE CAROL, CARMEL, NY	11/20/97
BANDY, BRIAN DWAYNE, ASHLAND, KY	11/20/97
BARNES, DAVID L, HAMMOND, LA	11/20/97
BATRA, KRISHAN KUMAR, ODESSA, FL	11/20/97
BEAUDOIN, GERARD MARCEL JR, EGLIN AFB, FL	11/20/97
BROWN, YVONNE, ROCKVILLE CENTRE, NY	11/20/97
BROYLES, STEPHEN R, TAMPA, FL	11/20/97
BUDDE, MICHAEL J, COLUMBIA, IL	11/20/97